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MAY 18 2006

Roger L. Browdy
Browdy and Neimark PLLC
624 Ninth Street NW
Suite 300
Washington DC 20001-5303

In Re: Patent Term Extension Application
for U.S. Patent No. 4,840,896

Dear Mr. Browdy:

An ORDER GRANTING INTERIM EXTENSION under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,840,896 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to Kathleen Kahler Fonda by telephone at (571) 272-7754, or by e-mail at kathleen.fonda@uspto.gov.

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Beverly Friedman

RE: OVIDREL®
FDA Docket No.: 2005E-0256

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Genzyme Corporation	:	
Request for Patent Term Extension	:	ORDER GRANTING
U.S. Patent No. 4,840,896	:	INTERIM EXTENSION

Genzyme Corporation, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,840,896, filed an application for patent term extension under 35 U.S.C. § 156 on November 20, 2000. The original term of the patent is due to expire on June 20, 2006. The patent claims the active ingredient choriogonadotropin alfa (recombinant human chorionic gonadotropin (r-HCG)), in the human drug product OVIDREL®, which was approved by the Food and Drug Administration for commercial marketing or use on September 20, 2000. An extension of 1,054 days was originally requested, but applicant's Request for Interim Extension Under 35 U.S.C. § 156(e)(2) of March 13, 2006, now requests an extension until April 28, 2009, (1,043 days) in view of the corrected regulatory period set forth in the Food and Drug Administration's (FDA) letter of February 24, 2006.

The initial USPTO review of the application to date indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. On March 15, 2006 (71 Fed. Reg. 50), the FDA published the determination of the regulatory review period for purposes of patent term extension for OVIDREL®, but this determination has not yet been made final. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,840,896 is granted for a period of one year from the original expiration date of the patent.

5/17/06
Date

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office